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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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December 5, 2008

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The Honorable Andrew von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Dr. von Eschenbach:

We are continuing to examine the management and operations of the FDA Office of Criminal Investigations (OCI). This request letter follows up in part to FDA's response letter of July 2, 2008, to us.

As we previously noted, in the course of the Committee's oversight of FDA, questions about the performance and accountability of the OCI have arisen in several investigations, and even in hearing testimony. In addition, as the Committee continues work on FDA-related legislation, there is oversight concern about OCI's growing budget at a time of constrained resources for other parts of FDA, and OCI's effectiveness in using its staff and resources.

In light of these concerns, the Committee needs additional information to make an accurate assessment of OCI's performance. To assist us in this examination, please provide the following:

1. How many OCI-only investigations for FY 2007 and FY 2008 resulted in declinations by U.S. Attorneys offices? How many OCI-only investigations for FY 2007 and FY 2008 resulted in prosecutions?
2. Have OCI agents detailed to FDA's Office of Internal Affairs conducted any investigations of allegations of misconduct involving OCI personnel? How many cases were there and what were the allegations and the results of the investigations? Were any cases referred to the Office of Inspector General, Department of Health and Human Services? Does the Office of Internal Affairs have any reporting relationship to the Office of Criminal Investigations?
3. According to a February 20, 2002, letter from Melinda Plaisier, then Associate Commissioner for Legislation, to the Honorable James C. Greenwood, then Chairman of the Subcommittee on Oversight and Investigations, "OCI has been granted hiring authorization for 33 new criminal investigator full-time equivalents (FTEs) for counter-terrorism." According to Tab C of the FDA's July 2, 2008, response, OCI has agents assigned to six Joint Terrorism Task Forces and

two agents assigned part time to the Virginia Anti-Terrorism Advisory Council. However, according to Tab D of the July 2, 2008, response, there is no case type listed for counterterrorism cases, and thus no breakdown is provided for the number hours logged for counterterrorism cases. Why has OCI not changed its codes to reflect the additional counterterrorism work after 9-11? Please provide any information and/or documents that would substantiate OCI's work on closed counter-terrorism cases since January 1, 2003.


4. How many FDA inspections of OCI field offices were conducted, if any, since January 1, 2007, assuming any were conducted? Where were the field offices? What subjects were covered by the inspections? Who conducted the inspections? What were the criteria for selecting the field offices for inspections?

In addition, we request the following documents:


1. A copy of the instructions or procedures for completing or coding special agent monthly activity worksheets, including all sets of instructions used by OCI special agents.
2. A written explanation or a pre-existing document supporting authority in the Federal Food, Drug, and Cosmetic Act for OCI's conduct of criminal investigations in areas other than counterfeit drugs.
3. Copies of all OCI manuals, including instruction handbooks for special agents and OCI field office manager manuals.
4. A copy of OCI's performance plan and/or work plan for FY 2008.

Please provide responses to the following by one month from the date of this letter. If you have any questions, please contact Mr. Alan Slobodin of the Minority Committee staff at (202) 225-3641.

Sincerely,



Joe Barton
Ranking Member



John Shimkus
Ranking Member
Subcommittee on Oversight & Investigations

cc: The Honorable John Dingell
Chairman
Committee on Energy and Commerce

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight & Investigations